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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,001	01/30/2002	Sau Lan Tang Staats	PST-100US	6603
7590 01/25/2005			EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			BARTON, JEFFREY THOMAS	
			ART UNIT	PAPER NUMBER
			1753	
DATE MAILED: 01/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/061,001	Applicant(s) STAATS, SAU LAN TANG	
	Examiner Jeffrey T. Barton	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,9-18,20-23,25-27,29,30,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,9-18,20-23,25-27,29,30,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed on 16 November 2004 does not place the application in condition for allowance.

Status of Objections and Rejections Pending Since the Office Action of

16 July 2004

2. All objections and rejections of claims 5-8, 19, 24, 28, 31, and 37 are obviated due to cancellation of the claims.
3. All objections to the specification and drawings, and the formal objections to claims 9 and 29 are withdrawn due to Applicants' amendment.
4. The rejection of claim 1 under 35 U.S.C. §112 (1) is maintained.
5. All rejections previously made under 35 U.S.C. §102 are withdrawn due to Applicants' amendment.
6. All rejections previously made under 35 U.S.C. §103(a) are withdrawn due to Applicants' amendment.

Claim Objections

7. Claims 1 and 17 are objected to because of the following informalities:
 - a. In claim 1 at line 1, "An microfluidic device" should be replaced with "A microfluidic device".

b. In claim 1, at line 14, "an extend outwardly" should be replaced with "and extend outwardly".

c. In claim 17, at line 3, it is not clear what is intended by, "the first channel which extends the top surface" - the claim is treated herein as though this read, "the first channel which extends across the top surface".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-4, 17, 18, 20, 25-27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ekström et al.

Regarding claim 1, Ekström et al disclose a microfluidic device (Figures 1 and 8) comprising an injection-molded article (Column 5, lines 48-57) having a substrate with a top surface and raised channel architecture as claimed (Figure 8; Column 9, lines 2-6); a cover positioned over the substrate in alignment with the substrate (Figure 8, plate 23); wherein the channel is accessed through an access port positioned on one of the plates (Column 9, lines 10-11); wherein the substrate and raised walls are formed of an injection-moldable polymeric material (Column 8, lines 55-61; Column 5, lines 48-57); and the raised walls are formed in a common mold in situ with the substrate such that

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the raised walls are integrally formed with and extend outwardly from the substrate.

(Column 8, line 52 - Column 9, line 6)

Regarding claims 2 and 3, Ekström et al disclose access ports on the channel bottom (Figure 9, aperture 27) or on the cover. (Figure 5, openings 14 and 15; Column 7, lines 29-33)

Regarding claim 4, Ekström et al disclose the sidewalls rising at an angle of approximately 90°. (Figure 8)

Regarding claims 17 and 20, Ekström et al disclose vertical stacking of channels, including conduits extending from the bottom of a channel to another channel. (Figure 7a; Column 8, lines 24-33) These conduits can be described as "interconnecting ducts".

Regarding claim 18, Ekström et al disclose incorporation of a detector window region in their device. (Column 9, lines 37-44)

Regarding claim 25, Ekström et al disclose a channel with perpendicular sections. (Figure 1, channel 4)

Regarding claims 26 and 27, Ekström et al disclose channels with these dimensions. (Column 7, lines 4-7)

Regarding claim 29, Ekström et al disclose using a material with low melt viscosity. (Column 4, lines 8-16)

Claim Rejections - 35 USC § 103

10. Claims 9-11 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekström et al in view of Kennedy. (US 5,876,675)

Ekström et al disclose a device as described above in the treatment of claims 1 and 29.

Ekström et al do not explicitly disclose a device further comprising a device adapted to align the cover with the substrate (Claim 9), where the device is a dowel pin on the substrate (Claim 10), where the device is a protrusion on the cover (Claim 11), or where the microfluidic device is molded from one of the listed materials of claim 30.

Regarding claims 9-11, Kennedy discloses alignment structures including pins with corresponding holes, or bevels, ridges, notches or tabs serving the same purpose (Column 10, lines 1-25)

Regarding claim 30, Kennedy et al disclose forming devices by injection molding using materials such as polymethylmethacrylate or polycarbonate. (Column 4, lines 8-16)

Addressing claims 9-11, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ekström et al by adding pins or other protrusions with corresponding recesses to complementary positions on the substrate and cover, as taught by Kennedy, because it would simplify proper assembly of the device. It would also be obvious to place pins or holes on either plate, as it is a matter of manufacturing choice, with no significant functional difference between options.

Addressing claim 30, it would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ekström et al by forming the device from polymethylmethacrylate or polycarbonate, as taught by Kennedy, because Kennedy teaches their advantages of low cost, disposability, and inertness. (Column 4, lines 17-19) Additionally, it would be within the ability of a skilled artisan to select a device material according to the requirements of the experiment.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekström et al and Kennedy as applied to claim 9 above, and further in view of Wu et al.

Ekström et al and Kennedy disclose a combination as described above in the treatment of claim 9.

Neither Ekström et al nor Kennedy explicitly disclose a device further comprising a device adapted to align the cover with the substrate (Claim 9) with accuracy better than 0.001 inch.

Wu et al disclose a means of aligning plates with accuracy better than 25 microns (0.001 inch). (Column 27, lines 19-20)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ekström et al and Kennedy by providing an alignment mechanism with accuracy better than 0.001 inch, as taught by Wu et al, because it would allow for more accurate alignment and consequent possibility for further miniaturization and avoidance of sample waste.

12. Claims 13, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekström et al in view of Kovacs et al.

Ekström et al disclose a device as described above in addressing claim 1.

Ekström et al do not explicitly disclose a device comprising a capillary positioned in the access port according to the limitations of these claims.

Relevant to claim 13, Kovacs et al disclose a microfluidic device (Figure 8) comprising a capillary (14) positioned in the channel access port (16) and inserted in the channel, wherein the access port diameter and the outer diameter of the capillary are approximately equal. (Figure 8, D1)

Relevant to claim 14, Kovacs et al further disclose the use of an adhesive to secure the outer circumference of the capillary to the access port. (Column 5, lines 26-32)

Relevant to claim 16, Kovacs et al disclose a microfluidic device comprising a capillary (14) positioned in the channel access port and inserted in the channel (Figure 8), wherein the capillary inner cross-sectional area and the channel cross-sectional area are approximately equal. (Figure 8, D2; Column 5, lines 59-65)

Addressing claims 13 and 14, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ekström et al by configuring the cover plate and including a feed capillary with a diameter that is precisely matched to the channel access port, as taught by Kovacs et al, because Kovacs teaches that it provides convenient, removable means of fluid ingress in such systems. (Column 1, lines 36-50; Column 2, lines 15-27)

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Addressing claim 16, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ekström et al by configuring the cover plate and including a feed capillary with a inner diameter that is precisely matched to the channel cross section, as taught by Kovacs et al, because it would reduce dead volume and provide more efficient and complete transfer of fluids into the microchannel.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekström et al and Kovacs et al as applied to claim 13 above, and further in view of Shartle et al.

Ekström et al and Kovacs et al disclose a combination as described above in addressing claim 13.

Neither Ekström et al nor Kovacs et al explicitly disclose the use of a transparent polymeric capillary in their devices.

Shartle et al disclose the use of transparent polymeric capillaries in an electrophoresis apparatus. (Column 4, lines 48-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Ekström et al and Parce et al by replacing the capillary with a transparent polymeric capillary, as taught by Shartle et al, because it would be flexible and easy to manipulate, and also reduce costs.

14. Claims 9, 11, 21-23, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekström et al in view of Bjornson et al.

Ekström et al disclose a device as described above in addressing claim 1. In addition, relevant to claim 23, Ekström et al show interstitial spaces between the plates along the outside surface of the channel sidewalls in figure 8. (outside of the protrusions of plate 21) Also, relevant to claims 38 and 39, Ekström et al disclose sidewalls seated flush against the bottom surface of the cover. (Figure 8)

Ekström et al do not explicitly disclose a device wherein the cover comprises a protrusion adjacent to the inner surface of the sidewall or wherein the cover comprises a protrusion adjacent to the outer surface of the sidewall, so as to enclose and seal the channel by providing a ceiling structure opposite the channel floor. (Claims 21 and 22)

Relevant to claims 21-23, Bjornson et al disclose a microfluidic device (Figures 10 and 11), which comprises a cover (620) and substrate (54), the cover comprising a protrusion (674) extending from its bottom surface, wherein the protrusion is adjacent the inner surface of the sidewall. (Interior of wells in plate 54) These protrusions are to aid in sealing the wells upon inversion of the plates, thus addressing the same problem to which the instant claims are directed. (Column 22, lines 29-51)

Relevant to claims 9 and 11, Bjornson et al also disclose the function of the protrusion in aligning the plates of the device. (Column 22, lines 51-54)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ekström et al by using protrusions from the cover aid in sealing the joint between the cover and substrate, as taught by Bjornson et al, because it would provide sealing without requiring external clamping means. Such a structure would provide a channel ceiling structure opposite the channel floor.

Regarding claim 22, it would also have been obvious to provide protrusions from the cover adjacent to the outer surface of the sidewall, because it is a matter of design choice with no apparent distinction in function.

Response to Arguments

15. Applicant's arguments with respect to the rejection of Claim 1 under 35 U.S.C. §112(1) have been considered, but are not persuasive. The claim, as amended, still indicates that the cover is injection-molded, because it is listed as subcomponent B of an injection-molded article. A possible amendment to address this would be to rephrase lines 1 and 2 of the claim to read: "A microfluidic device comprising: A) an injection molded article having a substrate with a top surface . . ."

16. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the weight to be given to the limitations concerning injection molding, in view of the added limitations in lines 12-14 of claim 1, which recite structure intimately related with the method of forming the product, weight is properly given to the structure recited (i.e. raised walls, integrally formed with and extend(ing) outwardly from the substrate), although the examiner still maintains that the structure of the product must ultimately be the basis of patentability. Applicant argued that the limitations given in the prior set of claims (i.e. an injection molded article formed from an injection moldable material) speak directly to the product itself, since it forecloses that the device is made

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of metal or that the sidewalls are separate members attached to the substrate.

(Amendment, Page 9) Injection molding of metal and numerous other materials is known and these limitations do not explicitly preclude the sidewalls being formed separately from the substrate. The structure of the product was in no way defined by these limitations. As Applicant's amendment includes new structural limitations (e.g. raised walls integrally formed with the substrate) that require a molding process (such as injection molding) much of the prior art applied in the previous action, such as Zanzucchi et al and Fuchs et al, has been overcome. However, the new rejections given above address the new limitations.

Regarding the use of Parce et al in rejecting claims 1 and 21-23, Applicant argued that their disclosure did not enable injection molding, but simply listed it among a large number of possible techniques, and furthermore, that the channels of Parce et al are recessed in the substrate, as opposed to the structure of the instant application, requiring raised walls. In view of the amendment to claim 1 requiring raised sidewalls, Parce et al no longer applies.

Also regarding the rejection of claims 21-23 as obvious over Parce et al in view of Jedrzejewski et al, the addition of the limitation that the cover protrusion is "received between the inner surfaces of the sidewalls . . . providing a channel ceiling structure opposite the channel floor" avoids the structure of Jedrzejewski et al, but again, the new rejection given above addresses the new limitations.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
January 18, 2005



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